



#11/Affidavit
Lauram
1-22-03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: STOLL, Thomas G

Serial No.: 09/489,982 Art Unit: 3626

Filed: January 21, 2000 Examiner: C. Bleck

For: DIGITAL PRESCRIPTION CARRIER AND MONITOR SYSTEM

STATE OF MISSOURI)
) ss.
COUNTY OF JACKSON)

AFFIDAVIT OF INVENTOR

Comes now the Applicant, Thomas G. Stoll, and states as follows:

1. No later than December, 1997 I invented the subject matter set forth in Claims 1-19 of the above-reference United States Patent Application.
2. While in the United States, I invented the subject matter set forth in each of the claims 1-19 of the above-referenced United States patent application.
3. No later than December 1997, I reduced to practice the following elements and method steps in combination:
 - (a) providing a digital prescription carrier including a read/write memory and a communication interface;
 - (b) uploading prescription data defining a prescription into said carrier through said interface, said prescription calling for the use of a selected medication of a selected dosage on a selected schedule;
 - (c) transferring said carrier by a patient to a pharmacy;
 - (d) downloading said prescription data from said carrier through said interface at said pharmacy; and
 - (e) filling said prescription at said pharmacy.

- (f) operating a digital clock/calendar within said carrier to generate internal values of time and date;
- (g) providing said carrier with a prescription compliance switch interfaced to said clock/calendar;
- (h) operating said compliance switch by a patient upon taking a medication specified by said prescription; and
- (i) storing in a compliance memory within said carrier respective values of time and date occurring upon operation of said compliance switch.
- (j) providing said carrier with an annunciator element;
- (k) entering into said carrier by said pharmacist schedule data defining a prescription schedule comprising a plurality of sets of schedule times and dates at which a patient is to take a medication specified by prescription;
- (l) periodically comparing within said carrier said internal values of time and date with said schedule times and dates; and
- (m) activating said annunciator element upon said internal values of time and date matching a set of said schedule time and schedule date.
- (n) providing said prescription carrier with an infrared data communication interface.
- (o) uploading prescription data defining a plurality of prescriptions for a plurality of medications into said carrier through said interface;
- (p) downloading said prescription data through said interface; and
- (q) filling each of said prescriptions defined by said prescription data.

3. No later than December, 1997, I reduced to practice the following elements of a digital prescription carrier apparatus:

- (a) a carrier housing;
- (b) a central processing unit (CPU) positioned within said housing;
- (c) a display device positioned on said housing, interfaced to said CPU, and capable of displaying alphanumeric characters;

- (d) input/output (I/O) interface circuitry positioned in said housing and interfaced to said CPU, said I/O circuitry being capable of interfacing said CPU to an external computer to exchange data therewith;
- (e) data memory circuitry positioned within said housing;
- (f) prescription software stored in said memory to be processed by said CPU, wherein, the CPU and the I/O circuitry cooperate to enable uploading, by a prescriber, of prescription data representing a prescription into said memory circuitry, and downloading of said prescription data at a pharmacy;
- (g) a real-time clock/calendar positioned within said housing and interfaced to said CPU;
- (h) an alert device positioned within said housing and interfaced to said CPU;
- (i) said prescription software cooperating with said prescription data, said clock/calendar, and said alert device to cause activation of said alert device when a dose of medication prescribed by said prescription data is to be taken;
- (j) a compliance switch positioned on said housing and interfaced to said CPU;
- (k) said prescription software cooperating with said compliance switch to record in said data memory circuitry an occurrence of the operation of said compliance switch subsequent to activation of said alert device;
- (l) a sonic alert device interfaced to said CPU;
- (m) a vibrating alert device interfaced to said CPU;
- (n) a plurality of key switches positioned on said housing and interfaced to said CPU;
- (o) said prescription software causing uploaded prescription data to generate a schedule of dose times for a medication represented by said prescription data;
- (p) operation of said key switches enabling review of said schedule of dose times for said medication in cooperation with said display device.

Affidavit of Thomas G. Stoll
cont'd

4. In support of my claim for prior invention, I have attached hereto the following documents:

- a. A flowchart detailing the elements of my invention, as set forth in paragraphs 2 and 3 above, was created no later than December, 1997. A true and correct copy of the flowchart is annexed hereto as Annex A. I had already invented and reduced to practice my invention, as set forth in paragraphs 2 and 3, prior to the making of the flow chart, which clearly establishes possession of the following claimed method steps:
 - i. providing a digital prescription carrier including a read/write memory and a communication interface;
 - ii. entering a first access code into said carrier to enable software access thereto;
 - iii. uploading prescription data defining a prescription into said carrier through said interface, said prescription calling for the use of a selected medication of a selected dosage on a selected schedule;
 - iv. downloading said prescription data from said carrier through said interface at said pharmacy; and
 - v. filling said prescription by said pharmacist.
 - vi. providing said carrier with an annunciator element;
 - vii. entering into said carrier by said pharmacist schedule data defining a prescription schedule comprising a plurality of sets of schedule times and dates at which a patient is to take a medication specified by said prescription;
 - viii. uploading, by a physician, prescription data defining a plurality of prescriptions for a plurality of medications to be

- taken on a plurality of schedules into said carrier through said interface;
 - ix. downloading, by a pharmacist, said prescription data through said interface;
 - x. storing in a compliance memory within said carrier respective values of time and date occurring upon operation of said compliance switch.
- b. After I reduced to practice my invention, as described in paragraphs 2 and 3 above, I privately disclosed my invention to Kemnitzer Design, Inc., a consulting engineering firm, to discuss alternatives for the physical appearance of my invention, and possible alternate embodiments. True and correct copy of correspondence from Kemnitzer Design, Inc., dated December 27, 1997, is attached hereto as Annex B.

Attention is invited to the following provisions of this letter, which evidence possession of the following elements of the invention:

- i. the housing (“... about the size of a pager...” Par. 1, line 3)
- ii. the central processing unit (“... the pharmacist ... can program this device through a PC...” Par. 1, line 11)
- iii. the display device integrated with the CPU (“... a two-line LED display that would ‘remind’ a user ...” Par. 1, line 4)
- iv. a sonic alert device interfaced to said CPU (“... the [device] would alert the user with an audible signal...” Par. 1, lines 5-6)

- v. a display device positioned on said housing, interfaced to said CPU, and capable of displaying alphanumeric characters (“...[device] would ... display a prescription dosage...” par 1, lines 5-6)
- vi. uploading, by a prescriber, of prescription data representing a prescription into said memory circuitry, and downloading of said prescription data at a pharmacy (“... the device retains a history of response that can be downloaded by the pharmacist...” Par. 1, lines 10-11)
- vii. data memory circuitry positioned within said housing (“The device retains a history of response...” Par. 1, line 10)
- viii. a plurality of key switches positioned on said housing an interfaced to said CPU (“... an enter button...” Par 1, line 7. “... a ‘snooze’ button...” Par. 1, line 9. “... ‘up’ and ‘down’ buttons...” Par. 1, line 12.
- ix. prescription software causing uploaded prescription data to generate a schedule of dose times for a medication represented by said prescription data. (“This is a product that would aid users in prescription compliance that would ‘remind’ the user of a prescription to be taken.” Par. 1, lines 2-4)
- x. a real-time clock/calendar positioned within said housing and interfaced to said CPU. (“This is a product that would aid users in prescription compliance that would ‘remind’ the user of a prescription to be taken.” Par. 1, lines 2-4).

- xi. input/output (I/O) interface circuitry positioned in said housing and interfaced to said CPU, said I/O circuitry being capable of interfacing said CPU to an external computer to exchange data therewith. ("The device retains a history of response that can be down loaded by the pharmacist, who can program this device through a PC." Par. 1, lines 10-11).
- c. After I had reduced to practice my invention, as set forth in paragraphs 2 and 3 of this Affidavit, I formed Medical Innovations, Inc., a Corporation existing under authority of Missouri law. It was my initial intent to make Medical Innovations, Inc. the sole owner and assignee of the rights in my invention. (However, because of the tax advantages of a limited liability company, I subsequently formed Next Med, LLC and assigned all rights in my invention thereto.) A true copy of a printout from the corporations database of the Missouri Secretary of State, verifying an incorporation date of May 9, 1997 is attached hereto as Annex C.
- d. A true copy of IRS Form 2553, dated March 14, 1998 and received by the IRS on March 18, 1998, is attached hereto as Annex D.
- e. Faxed correspondence from an engineer/draftsman to me, dated September 25, 1998, informing that he had completed drawings of my invention, as set forth in paragraphs 2 and 3 of this Affidavit, of the above-referenced United States Patent Application. True and correct copies of the facsimile transmission are attached hereto as Annex E.


Affidavit of Thomas G. Stoll
cont'd

- f. Correspondence from me to my patent agent, together with enclosures, dated October 1, 1998, informing that diagrams and drawings of my invention had been completed. True and correct copies are attached hereto as Annex F.

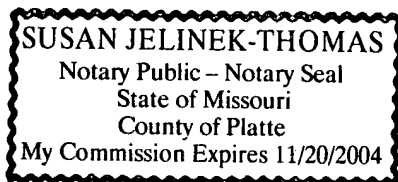
5. No later than December 1997, I acquired possession of either the whole invention claimed or something falling within the claim, in the claims, as a whole read directly on the device and method I invented.

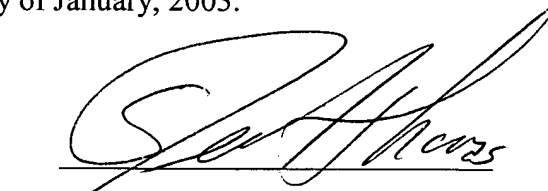
The flow chart was not intended to fully capture every element of my invention, but was only intended to provide a basic understanding of several elements thereof.

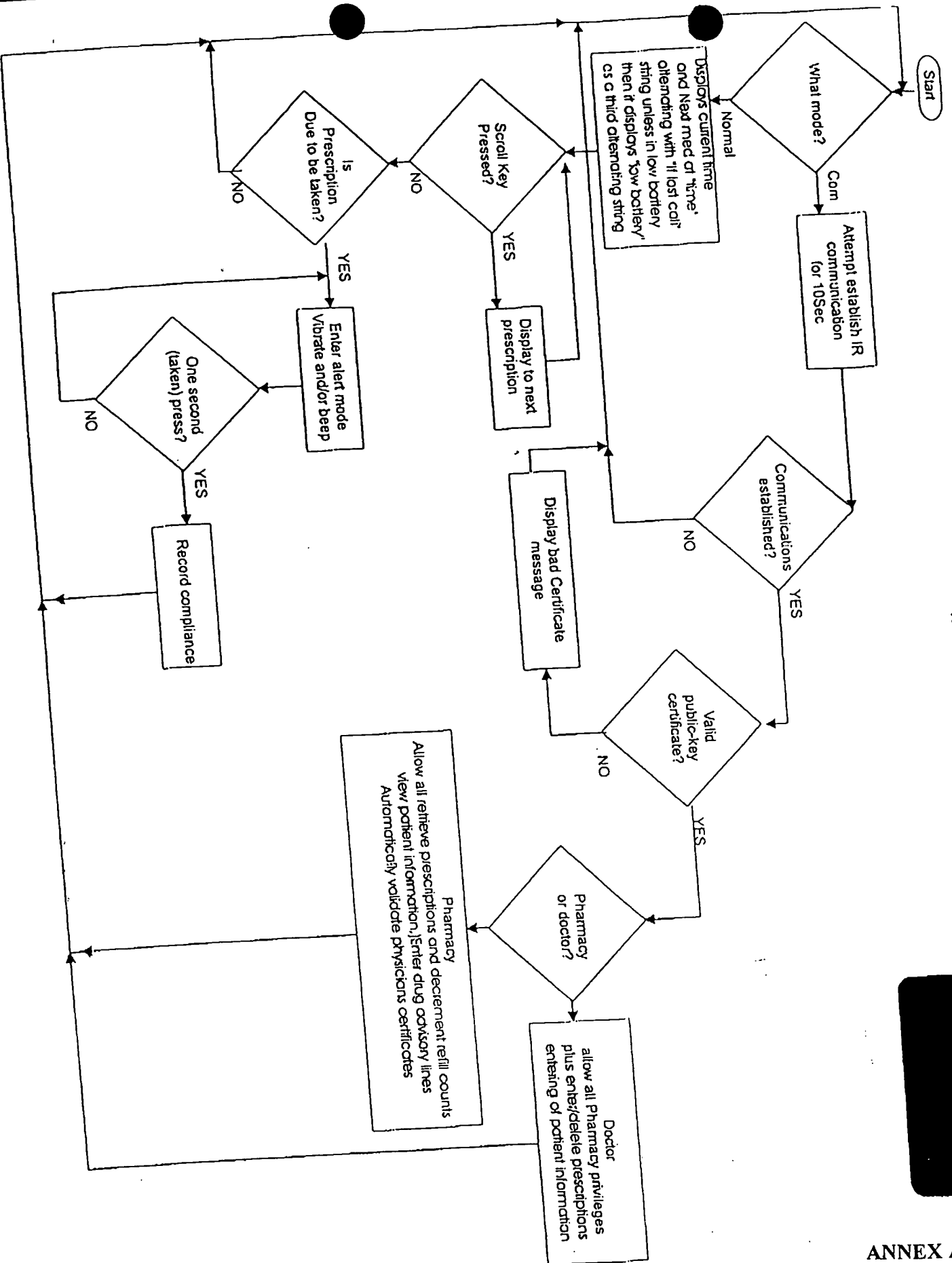
Under the penalty of perjury, I hereby affirm that each of the above and foregoing statements is true and correct to the best of my knowledge and belief.


Thomas G. Stoll, applicant

Subscribed and sworn to before me this 14th day of January, 2003.




Notary Public



Proposal For Industrial Design Assistance
Medi-Minder
 Medical Innovations, Inc.

Submitted to: Mr. Thomas G. Stoll
 Medical Innovations, Inc.
 c/o Kurlbaum Stoll Seaman Suter & Mustoe, PC
 City Center Square
 1100 Main, Suite 2001
 Kansas City, MO 64105

Date: December 27, 1997

Project Overview:

Medical Innovations, Inc. is a new company that has generated a new product concept called the 'Medi-Minder'. This is a product that will aid users in prescription compliance. As conceived by Medical Innovations, Inc., the product would be the size of a pager. It would have a battery powered, two line LED display that would 'remind' the user of a prescription to be taken. At the prescribed time for the dosage, the Medi-Minder would alert the user with an audible signal and a display of prescription dosage. An illuminated red light will reinforce the event. When the user has taken the prescription, they press an 'enter' button for one second to acknowledge consumption of the dosage. If the user can not immediately respond to the alert, they can press a 'snooze' button that will cause the device to pause for three minutes before reminding the user again. The device retains a history of response that can be down loaded by the pharmacist, who also can program this device through a PC. The unit will have 'up' and 'down' buttons to view past and future prescription dosages.

About Kemnitzer Design:

Kemnitzer Design, Inc. is an eight person industrial design consulting office located in Overland Park, Kansas. Our work has been cited by such prestigious sources as 'Business Week' magazine and the Industrial Designers Society of America. Our experience is broad with work completed in electronic products, sporting goods, appliances, medical equipment, commercial office furniture, retail merchandising systems, and other areas of design. We are particularly interested in projects that require the thoughtful and creative combination of mechanical design, human factors, manufacturability, creative material selection, appearance and cost. We have ongoing and active associations with consulting engineers with expertise in mechanical, electrical, RF, production, and materials engineering. We contract expert resources in finite element analysis and mold flow analysis when necessary. Additionally, we utilize the services of several patent attorneys and market research analysis firms. We worked closely with one of our market research affiliates recently in the development of a laser rangefinder for Bushnell that was given the First Place Buyer's Choice Award by Cabela's, the leading sports equipment direct seller in the US.

Medical Innovations, Inc. wishes to solicit input from potential users and prescribers prior to committing to a formal design/build program. Accordingly, it has asked Kemnitzer Design, Inc. (KDI) to prepare a proposal for production of a non-functional visual model. KDI is pleased to respond with the following proposed course of action, timeline and cost:

Phase I. Conceptual Design and Prototype Production.

Kemnitzer Design, Inc. (KDI) will design 2 versions of the product that will each represent functional design principles, but will offer distinct differences in visual image, feel to the hand,

ANNEX B

10880 Benson Drive, Suite 2300
 Overland Park, Kansas 66210
 913 ~~338-2404~~
 FAX 338.2461
 kdesign@cz.sunflower.org

BEST AVAILABLE COPY

and operational control/functional interface. By producing 2 visual prototypes, it is our opinion that evaluators will have the opportunity of comparison which will elicit more thoughtful considerations and suggestions. Through these suggestions and discussions, it is highly likely that clear functional, operational and aesthetic criteria for the manufactured version will emerge.

Phase I Deliverables:

1. Two non-functional, 3-dimensional visual prototypes.

Time required to complete this phase: 2 weeks (10 working days).

Project Budget:

Kemnitzer Design, Inc.'s compensation for services rendered is based on hourly rates of \$125 Principal, \$85 Senior Designers, \$50 Designers and \$75 Prototyping Studio. Performing services on a fixed fee basis is acceptable to Kemnitzer Design and the following amounts are offered for the phase described in this proposal:

Phase 1: **\$4830.00**

This price is based on currently understood goals and criteria for this product. If criteria and goals change significantly during the course of the project, Kemnitzer Design, Inc. reserves the right to revise these costs as appropriate and with the consent of Medical Innovations, Inc.

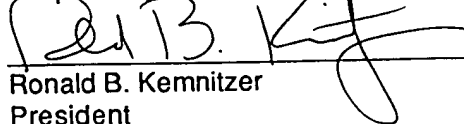
Intellectual Property:

On completion of the timely payment for services rendered, all concepts (mechanical and aesthetic) that are incorporated into the final designs as produced will be the exclusive property of Medical Innovations, Inc. Kemnitzer Design, Inc. will co-operate in the process of patent and copyright applications as requested and will assign all rights of invention to Medical Innovations, Inc. at no additional cost. Medical Innovations, Inc. will assume all costs of filing and defending said patents and copyrights.

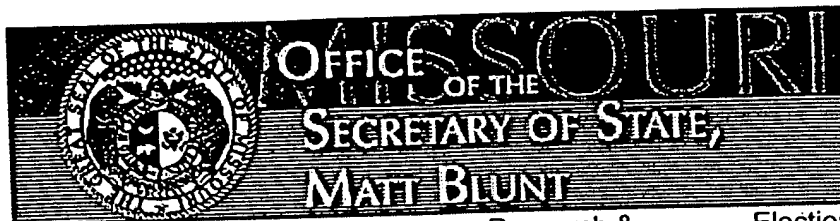
Terms:

- Kemnitzer Design, Inc. will require a 50% prepayment (\$2,415.00) of Phase I and a purchase order to begin work on this project.
- This project may be terminated by Medical Innovations, Inc. at any time with no obligation beyond payment for work completed based on our normal hourly fees.
- Kemnitzer Design, Inc. will incur no extraordinary reimbursable expenses without prior authorization or approval by Medical Innovations, Inc.
- All expenses such as postage, shipping, materials, long distance telephone, travel, blueprints, etc. incurred in the completion of this project will be reimbursed at cost by Medical innovations, Inc.
- If the project criteria and/or output requirements change significantly during the course of a fixed fee phase, Kemnitzer reserves the right to adjust the fee accordingly with prior approval of Medical Innovations, Inc.
- Invoices are due on receipt. All accounts unpaid after 30 days are charged interest at the rate of 18% annually (1.5% monthly).

Respectfully submitted,



Ronald B. Kemnitzer
President
Kemnitzer Design, Inc.


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Business Entity Database Search

[Corporations](#) | [Business Services](#)

Business Entity with Charter Number CC0440995

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Name MEDICAL INNOVATIONS, INC.

Street		City/State/Zip	
Business Type	Close Corporation	State of Incorporation	MO
Status Date	09/14/1999	Status	DF
Registration Date	05/09/1997	Current Name Date	05/09/1997
Expiration Date	Perpetual	Report Period	01/01 : 12/31
Last AR Filed	08/10/1998	Last AR Year	1998

Agent Information

Name Thomas G. Stoll	Authorization Date
Street 1100 Main Str., Ste. 2001	City/State/Zip Kansas City, MO 64105

Status History | **Name History**

Produce Annual Report for Current Fiscal Tax Year
(Internet Explorer 4.x & 5.x Only)

[Business Entity Search](#) | [Agent Name Search](#) | [Charter Number Search](#)

[Office Information](#) | [Business & Investing](#) | [Research & Reference](#) | [Elections & Voter Info](#) | [Young Missourians](#) | [Gov-to-Gov](#)
[Missouri State Government Web]

ANNEX C

Election by a Small Business Corporation

(Under section 1362 of the Internal Revenue Code)
▶ For Paperwork Reduction Act Notice, see page 2 of instructions.
▶ See separate instructions.

OMB No. 1545-0146

- Notes: 1. This election to be an S corporation can be accepted only if all the tests are met under Who May Elect on page 1 of the instructions; all signatures in Parts I and III are originals (no photocopies); and the exact name and address of the corporation and other required form information are provided.
2. Do not file Form 1120S, U.S. Income Tax Return for an S Corporation, for any tax year before the year the election takes effect.
3. If the corporation was in existence before the effective date of this election, see Taxes an S Corporation May Owe on page 1 of the instructions.

Part I Election Information		
Please Type or Print	Name of corporation (see instructions) <u>Medical Innovations, Inc.</u>	A Employer identification number <u>43-1803808</u>
	Number, street, and room or suite no. (If a P.O. box, see instructions.) <u>1100 Main ST Suite 2001</u>	B Date incorporated <u>May 9, 1997</u>
	City or town, state, and ZIP code <u>Kansas City, MO. 64105</u>	C State of incorporation <u>Missouri</u>
D Election is to be effective for tax year beginning (month, day, year) <u>1998</u>		F Telephone number of officer or legal representative <u>816-221-5444</u>
E Name and title of officer or legal representative who the IRS may call for more information <u>Thomas G. Stoll, President</u>		
G If the corporation changed its name or address after applying for the EIN shown in A above, check this box <input type="checkbox"/>		
H If the election takes effect for the first tax year the corporation exists, enter month, day, and year of the earliest of the following: (1) date the corporation first had shareholders, (2) date the corporation first had assets, or (3) date the corporation began doing business <u>1-1-98</u>		
I Selected tax year: Annual return will be filed for tax year ending (month and day) <u>1998</u> If the tax year ends on any date other than December 31, except for an automatic 52-53-week tax year ending with reference to the month of December, you must complete Part II on the back. If the date you enter is the ending date of an automatic 52-53-week tax year, write "52-53-week year" to the right of the date. See Temporary Regulations section 1.441-2T(e)(3).		

J Name and address of each shareholder, shareholder's spouse having a community property interest in the corporation's stock; and each tenant in common, joint tenant, and tenant by the entirety. (A husband and wife (and their estates) are counted as one shareholder in determining the number of shareholders without regard to the manner in which the stock is owned.)	K Shareholders' Consent Statement. Under penalties of perjury, we declare that we consent to the election of the above-named corporation to be an S corporation under section 1362(a) and that we have examined this consent statement, including accompanying schedules and statements, and to the best of our knowledge and belief, it is true, correct, and complete. We understand our consent is binding and may not be withdrawn after the corporation has made a valid election. (Shareholders sign and date below.)		L Stock owned		M Social security number or employer identification number (see instructions)	N Shareholder's tax year ends (month and day)
	Signature	Date	Number of shares	Dates acquired		
<u>Thomas G. Stoll</u> <u>7601 Constance</u> <u>Lenexa, KS 66216</u>	<u>Tom Stoll</u>		<u>100</u>	<u>1-1-98</u>	<u>494-668429</u>	<u>12/31</u>

Under penalties of perjury, I declare that I have examined this election, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct, and complete.

Signature of officer Tom Stoll Title President Date 3-14-98

See Parts II and III on back.
ISA
STF FED4589F.1

Form **2553** (Rev. 9-97)

ANNEX D

Transtronics®

3209 West 9th Street Lawrence, Kansas 66049 USA
E-mail karl@xtrronics.com Web www.xtrronics.com

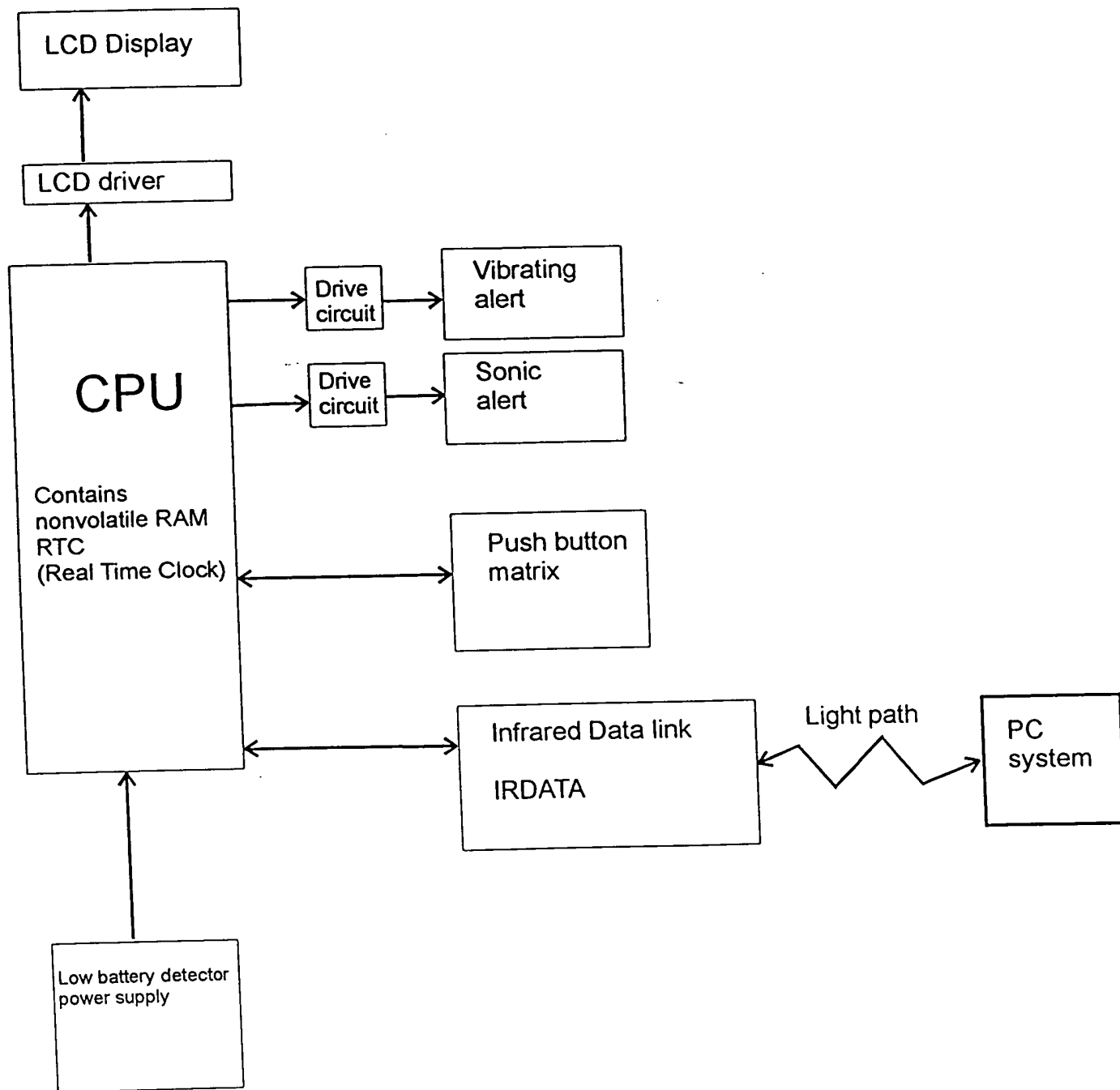
FAX

To: Thomas Stull (Business Fax)
Company:
Business phone: (816) 221-5444
Fax number: +1 (816) 474-6822

From: Karl Schmidt
Fax number: +1 (785) 841 0434
Business phone: (785) 841 3089
Date & Time: 9/25/98 4:50:41 PM
Pages sent: 6
Re:

ANNEX E

MED_x System™



**KURLBAUM STOLL SEAMAN
& MUSTOE, P.C.**
Attorneys at Law

*City Center Square
1100 Main, Suite 2001
Kansas City, MO 64105*

*Telephone (816) 221-5444
Telecopy (816) 474-6822*

Thomas G. Stoll

October 1, 1998

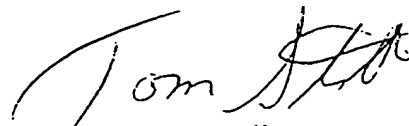
Mr. Dennis Crawford
Litman, McMahon & Brown, L.L.C.
4700 Bellview
Suite 200
Kansas City, MO 64112

Re: Medical Innovations, Inc.

Dear Dennis:

Enclosed is a block diagram, a rough sketch and a design outline for the MedX product. These items were prepared by Karl Schmidt, an electrical engineer helping with the product's design. The product's final appearance will be different than the sketch, but the sketch may help you conceptualize the product. After the electronic design is complete an industrial designer will help create the product's overall appearance. Please advise if this information is sufficient for you to go forward with the patent application. I understand from our conversations that you are reasonably confident that the patent application will be approved. Thank you.

Yours very truly,



Thomas G. Stoll

encls.

ANNEX F

Product Design Outline

1) The Med_x System™ Product Description

2) Hardware

a) Environmental

i) Normal consumer temperature range

ii) Normal UV rating?

b) Circuit board

i) Push buttons (4) large rubber like

ii) Recessed switch to select vibrator or sonic alarm 3 position switch with both alarm position

(1) Scroll up and down (2)

(2) 'take' Button

(3) snooze button

iii) LCD display

1) 2 lines X 16 characters of large print, Special symbols in later design for noncompliance, etc. off the shelf LCD for now.

(3) Back light activated by separate button

iv) IRDATA infrared data interface - base rate

v) Micro computer

vi) Nonvolatile memory

vii) RTC (real time clock)

viii) Low batter detector, power supply

ix) LCD driver chip

x) Sound driver transistor

xi) Vibration driver transistor

c) Battery holder

i) AAA preferred

ii) Battery life expectancy 2 Months

d) Vibrator

e) Sound transducer - peizo? Two tone feasable

f) Case

i) Size is about 3" X 2 X 1/2"

ii) Key chain attach point

iii) Weight about 3 Ounces

iv) Black high impact (ABS)

3) Software

a) I/O drivers

i) IR data

ii) Keyboard scan

iii) Sound driver

iv) Vibration driver

v) LCD driver

vi) RTC

vii) Low battery

b) Main functions

i) Normal mode

(1) Displays current time - and Next med at "time" alternating with "If lost call" string unless in low battery - then it displays "low battery" as a third alternating string

(2) Pressing one scroll key will allow patient to scroll thorough patent address / phone number (4 lines?) (If public) prescription information in order of when dosages are taken beginning at midnight. This line begins with an asterisk if drug is currently due to be taken. (Each drug line is followed by optional advisory line(s)? i.e. 'caution may cause drowsiness') - drugs are followed by patient information lines 500+ characters accessible with a 4 digit code - if so programmed.

(3) Pressing both scroll keys at once causes it to enter IR communication mode

(4) If a Medication becomes due - it enters alert mode

ii) IR communication mode

(1) Attempts to establish communications over IR port for 10Sec - If unable reverts to normal mode

(a) Requires a valid certificate to activate

(b) In this mode Physicians software with a "public Key" certificate can:

(i) enter/delete prescriptions (Up to 12 drugs can be entered), and patient information

(ii) automatically sets RTC via his computers clock.

(c) In this mode pharmacists can:

(i) retrieve prescriptions and decrement refill counts

(ii) view patient information

(iii) Enter drug advisory lines

(iv) Automatically validate physicians certificates

(v) Automatically sets RTC according to local computers clock

iii) Alert mode

(1) First activates vibration alarm - if confirm indication doesn't come it will activate the sonic alarm after 7 Min.

(2) Display scrolls to drug preceded by an asterisk

(3) Pressing snooze button while in alert mode will cause alarm to delay for 15 minuets After 4 snooze presses display will indicate (how?) noncompliance. - (occasional short chirps would not run the battery down very fast??) show hours from last pill

(4) Pressing the confirm button for one full second will:

(a) Sound a short chirp flash display

(b) Record compliance (How many compliance's can be stored?)
>1500

(c) Cancel alert

iv) Factory self Test mode

(1) When power is first applied pressing buttons in order will put unit into self test mode which will:

- (a) Perform a display test (display error codes)
- (b) Sound transducer (chirp error code?)
- (c) Test vibrator
- (d) Test IR link
- (e) Test RAM and flash
- (f) Return checksum and error codes over IR link

Preliminary block diagram of MED_x System™
MED_x System™

